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| APPLICATION NO.  | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|--|-------------|----------------------|---------------------|------------------|
| 10/615,966   | 07/09/2003  | Steven M. Watkins    | 2501331-991111      | 3383             |
| 7590   | 07/06/2005  |                      | EXAMINER            |                  |
| MORGAN LEWIS & BOCKIUS LLP<br>ONE MARKET STREET<br>SPEAR STREET TOWER<br>SAN FRANCISCO, CA 94105 |             |                      |                     | GITOMER, RALPH J |
|  |             | ART UNIT             |                     | PAPER NUMBER     |
|  |             | 1655                 |                     |                  |

DATE MAILED: 07/06/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

|                              |                                  |                         |
|------------------------------|----------------------------------|-------------------------|
| <b>Office Action Summary</b> | <b>Application No.</b>           | <b>Applicant(s)</b>     |
|                              | 10/615,966                       | WATKINS, STEVEN M.      |
|                              | <b>Examiner</b><br>Ralph Gitomer | <b>Art Unit</b><br>1651 |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on 09 July 2003.
- 2a) This action is FINAL.                    2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 1-75 is/are pending in the application.
- 4a) Of the above claim(s) 20-75 is/are withdrawn from consideration.
- 5) Claim(s) \_\_\_\_\_ is/are allowed.
- 6) Claim(s) 1-19 is/are rejected.
- 7) Claim(s) \_\_\_\_\_ is/are objected to.
- 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All    b) Some \* c) None of:
  1. Certified copies of the priority documents have been received.
  2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

|   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)  | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

Please update the specification regarding continuing information. And please inform the examiner as to any other related cases, pending, allowed or abandoned.

Applicant's election without traverse of Group I, claims 1-19, in the reply filed on 5/25/05 is acknowledged.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-4, 9-10, 18 are rejected under 35 U.S.C. 102(b) as being anticipated by Konrad.

Konrad (Biochimica et Biophysica Acta) entitled "Use of Deuterium Oxide to Measure de novo Fatty Acid Synthesis in Normal Subjects Consuming Different Dietary Fatty Acid Composition" teaches in the abstract, effect of dietary C18:2n-6 and C16:0 on the rate of hepatic fatty acid synthesis. Triacylglycerol levels were determined.

All the features of the claims are shown by Konrad for the same function as claimed.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 5-8, 11-17, 19 are rejected under 35 U.S.C. 103(a) as being unpatentable over the combination of Konrad in view of each of Reo, DeLong, and Watkins.

The claims differ from Konrad in that they specify the particular pathway by which the marker is converted into the product. Konrad specifies no pathways, only the reaction that takes place which must inherently occur along some pathway.

Reo (*Biochimica et Biophysica Acta*) entitled "Kinetic Analyses of Liver Phosphatidylcholine and Phosphatidylethanolamine Biosynthesis Using <sup>13</sup>C NMR Spectroscopy" teaches in the abstract, CDP-choline and PEMT pathways are studied with labeled choline and ethanolamine. The phosphatidylcholine produced was determined. On page 176 in Table 1 various metabolites were determined.

DeLong (*J of Biological Chem*) entitled "Molecular Distinction of Phosphatidylcholine Synthesis between the CDP-Choline Pathway and Phosphatidylethanolamine Méthylation Pathway" teaches in the abstract, two pathways to produce phosphatidylcholine were determined. D9-choline and D4-ethanolamine were employed. On page 29684 column 1 tritium labeled precursors and deuterium labeling are shown. On page 29686 Table 1 shows resulting products from the pathways. On page 29686 column 2 turnover of the species is discussed.

Watkins (Lipids) entitled "Unique Phospholipid Metabolism in Mouse Heart in Response to Dietary Docosahexaenoic or Alpha-Linolenic Acids" teaches on page 253, the results of the study indicate PEMT activity takes place in the heart and CDP-choline in the lung. The heart accumulated 22:6n-3 in response to dietary 18:3n-3. This was determined by feeding two different fatty acids, 22:6n-3 and 18:3n-3 and determining fatty acid composition of the heart, see Table 2 on page 249.

It would have been obvious to one of ordinary skill in this art at the time the invention was made to determine the contribution of a specific lipid in any known pathway to synthesize a fatty acid by determining the level of the marker composition of the precursor relative to the level of the marker composition in the synthesized fatty acid to indicate the contribution of the pathway to the synthesis of the fatty acid because each of the above references performs the steps of reacting a marker lipid in some pathway and determining the level of the marker lipid in the resulting product. Each of the above secondary references discusses the implications of the contribution of the pathway of interest to the synthesis of the product. The primary reference employs the same marker as presently claimed to determine which precursors are employed in a given unspecified pathway to produce triacylglycerol. The secondary references also employ a marker to determine some factor in a specified pathway to produce fatty acids.

Historically, there are a number of methods employed to delineate biochemical pathways and one of them is to provide a marked reagent, react it within some pathway, and determine the product produced within the pathway. The present claims are directed to a specific marked reagent which is shown by Konrad. The type of cells

selected that perform lipid synthesis would have the expected result and no novelty is seen in selecting plasma cells for example as claimed in claim 19. All the presently claimed pathways are known regarding what reactants produce what products. Regarding claims 5-8 directed to more than one marker composition, the secondary references above teach more than one marker composition as well as more than one product produced is determined. No novelty is seen in the selection of any of the claimed precursors.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-19 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Each of the following applies in all occurrences.

There are many instances of lack of antecedent basis in the claims that require correction, in claim 1 line 1 "the contribution", "the biosynthesis" for example. In claim 1 "a lipid class" is queried and is not understood in context. In claim 1 "a marker composition in a precursor" is indefinite as to what may be intended. No precursor of anything is seen.

The title of the invention is not descriptive. A new title is required that is clearly indicative of the invention to which the claims are directed.

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Mendrick (US 2002/0119462 A1) teaches modeling fatty acid metabolism.

Dickson (5,869,304) teaches fatty acid pathways.

Small (6,248,553) teaches determining lysophospholipids.

Leyland-Jones (US 2003/0190671 A1) teaches lipid metabolism.

Connor (Preparative Biochemistry) teaches labeled phosphatidylcholine.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ralph Gitomer whose telephone number is (571) 272-0916. The examiner can normally be reached on Monday - Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn can be reached on (571) 272-0926. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Art Unit: 1651

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Ralph Gitomer  
Primary Examiner  
Art Unit 1651

RALPH GITOMER  
PRIMARY EXAMINER  
GROUP 1200